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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,939	02/14/2007	Frederik W. Van Ginkel	20674-0003US1	2227

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
06/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/578,939	VAN GINKEL ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-125* is/are pending in the application.

4a) Of the above claim(s) *20-37 and 46-125* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-19 in the reply filed on April 3, 2009 is acknowledged. ***In view of Applicants amendment to claim 38 (Group IV) claims 38-45 will be rejoined with the elected Group I.***

The traversal is on the ground(s) that the Examiner has failed to explain why each group lacks unity with each other group, and thus is improper. Applicants further assert that the claims are drawn to a special technical feature, i.e., the *detoxified* neuramidase, which is novel over WO 02/077021. Finally, Applicants assert, that as described in the specification (Page 45) that pneumococci NanA mutants were recovered from tissues in far fewer numbers than wildtype pneumococci, the result of a technical advantage from using detoxified pneumococcal neuraminidase to provide immune protection. This is not found persuasive because as provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, ***makes over the prior art***. (Emphasis added). Applicants suggestion of a combination of Groups I and III (product and process of use)

are permitted unity of invention only when the claimed product is not disclosed in the prior art. Applicants will respectfully find multiple 102 rejections below, which defeat unity of invention. Furthermore, each of Group VII and XI are directed to structurally distinct compositions, which again do not share unity of invention in view of the prior art disclosing the first identified product. Second, Applicants further assert that the claims are drawn to a special technical feature, i.e., the *detoxified* neuramidase, which is novel over WO 02/077021. However, Applicants are respectfully directed to the teachings of WO 02/077021 (page 1 and claims) which specifically claims pneumococcal neuraminidase fragments as small as 7 consecutive amino acids. Applicants specification (page 15) defines "detoxification" as a "reduction or elimination in enzymatic activity." Applicants specification further sets forth that this is accomplished via substitution, ***deletion*** or alteration of amino acids in the active site of the neuramidase. (Emphasis added). As WO 02/077021 contemplates pneumococcal neuraminidase N-terminal signal peptides of 7 amino acids (i.e., deletion of "active site of neuramidase"); this fragment will inherently be identical to the claimed "detoxified pneumococcal neuramidase or antigenic portion thereof." Finally, Applicants assert, that as described in the specification (Page 45) that pneumococci NanA mutants were recovered from tissues in far fewer numbers than wildtype pneumococci, the result of a technical advantage from using detoxified pneumococcal neuraminidase to provide immune protection. However, while a "technical advantage" may be considered pertinent to overcoming a rejection under 35 USC 103, it cannot be used to overcome a 35 USC 102 rejection, furthermore Applicants will appreciate that not a single one of the

recited claims mention "NanA" or even more specifically the structure of the mutated NanA.

Accordingly, claims 1-125 are pending in the instant application, of which claims 20-37 and 46-125 are withdrawn from further consideration as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

1. Claims 1-19 and 38-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-19 and 38-45 recite a "detoxified pneumococcal neuraminidase or an antigenic portion thereof."

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "detoxified pneumococcal neuraminidase"

alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. There is no teaching regarding which amino acids are substituted, altered or deleted to result in a detoxified pneumococcal neuraminidase. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the

recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, the guidelines can be found at the following link on the USPTO Internet in "Patents Guidance" Specifically, Example 10, which is analogous to the claimed product of undefined structure identified solely by a particular function.

<http://www.uspto.gov/web/patents/guides.htm>

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 18-19, 38 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuomanen et al.

The claims are directed to a detoxified pneumococcal neuraminidase or an antigenic portion thereof.

Tuomanen et al (US Patent Number 5,792,457) disclose of heat killed pneumococcus strain R6 in saline. (See example 10).

Applicants specification (page 18) sets forth that the neuraminidase can be detoxified by chemical treatment and specifically contemplates heat treatment (Line 16).

Given that pneumococcus strain R6 inherently contains neuraminidase enzymes and that the strain was heat killed, a detoxified (heat killed) pneumococcal neuraminidase was inherently produced by Tuomanen et al.

3. Claims 1-19, 38 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Masignani et al.

The claims are directed to a detoxified pneumococcal neuraminidase or an antigenic portion thereof.

Masignani et al (WO 02/077021) disclose of pneumococcal neuraminidase fragments (as small as 7 consecutive amino acid residues) for vaccination purposes. (See page 1 and claims).

Applicants specification (page 15) defines “detoxified” as a reduction or elimination in enzymatic activity.” Applicants specification further sets forth that this is accomplished via substitutions, ***deletions***, or alterations of amino acids in the active site of the neuraminidase." (Emphasis added).

Given that Masignani et al contemplate pneumococcal neuraminidase fragments (ranging from 7, 8, 10…30, 40, 50 amino acids, etc) starting at the N terminus, which

would inherently be lacking the "active site of the neuraminidase" (i.e., detoxified) the disclosure of Masignani et al is deemed to anticipate the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-19 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masignani et al in view of Lee et al.

The claims are directed to a detoxified pneumococcal neuraminidase or an antigenic portion thereof, and wherein the neuraminidase is present in a nasal spray or nebulizer.

The teachings of Masignani et al are set forth above.

Masingnani et al do not teach of pneumococcal neuraminidase present in a nasal spray or nebulizer.

Lee et al (US Patent Number 7,202,056) disclose that at the time of the instant invention it was routine in the art to administer polypeptides for eliciting an immune response via nasal sprays or nebulizers. (See paragraph 0605).

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have taken the immunogenic polypeptides disclosed by Masingnani et al and create compositions for administration via nasal spray or nebulizer as taught by Lee et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
May 27, 2009